

clude ascertainment of the donor's identity and adequately completed and accurately recorded relevant medical history which assures freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection. For corneal retrieval which occurs under authorization of a specific State or territorial law the relevant medical history shall include all available medical, coroner, and autopsy records.

(f) Banked human tissue for transplantation shall be quarantined or accompanied by records of the donor's relevant medical history as defined in paragraph (e) of this section which assure freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection.

#### **§ 1270.7 Written procedures.**

(a) There shall be written procedures prepared and followed for all significant steps in the infectious disease testing process under § 1270.5 which shall conform to manufacturers' instructions for use contained in the package inserts for the required test kits. These procedures shall be readily available to the personnel in the area where the procedures are performed, unless impractical. Any deviation from the written procedures shall be recorded and justified.

(b) There shall be written procedures prepared and followed for all significant steps for determining the medical history of the donor as provided in § 1270.5. Such procedures shall be readily available to personnel who may perform the procedures. Any deviation from the written procedures shall be recorded and justified.

(c) In conformity with this section, any facility may use current standard written procedures such as those in a technical manual prepared by another organization, provided the procedures are consistent with and at least as stringent as the requirements of this part.

#### **§ 1270.9 Records, general requirements.**

(a) Records shall be maintained concurrently with the performance of each significant step required in this part in the performance of infectious disease

screening and testing of donors of human tissue for transplantation. All records shall be accurate and indelible and legible. The records shall identify the person performing the work, the dates of the various entries, and shall be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular tissue involved.

(b) All banked human tissue shall be quarantined until:

(1) All infectious disease testing under § 1270.5 has been completed, reviewed by a responsible official, and found to be negative;

(2) Donor screening has been completed, reviewed by a responsible official, and determined to assure freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection; and

(3) Copies of the testing and screening records accompany the tissue.

(c) All records, or true copies of such records, required under this part shall be readily available for authorized inspection at any establishment or from any individual that recovers, processes, stores, or distributes banked human tissue. Records that can be immediately retrieved from another location by electronic means meet the requirements of this paragraph.

(d) Records required under this part may be retained electronically, or as original paper records, or as true copies such as photocopies, microfiche, or microfilm, in which case suitable reader and photocopying equipment shall be readily available.

(e) Records shall be retained for no less than 10 years.

#### **§ 1270.11 Specific records.**

Records shall be maintained which include:

(a) Results and interpretation of all required infectious disease tests and retests.

(b) The destruction or other disposition of unsuitable banked human tissue.

(c) Information on the identity and medical history of the donor, as required by § 1270.5(e) in English or, if in another language, accompanied by a verified translation.